Materials and Design 31 (2010) 3982–3988

Contents lists available at ScienceDirect

Materials and Design

journal homepage: www.elsevier.com/locate/matdes

Technical Report

Medical design: Direct metal laser sintering of Ti–6Al–4V

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ARTICLE INFO

Article history:
Received 1 December 2009
Accepted 26 February 2010
Available online 7 March 2010

ABSTRACT

Design and manufacturing of customized implants prior to surgery are described in this study. Implant shape and functional requirements are established by digital data based on CT scans and mirroring operations. The design process of customized mandible prosthesis is illustrated as well as its manufacturing process (direct metal laser sintering) and dimensional control. Laser sintering process and its constraints for the production of customized implants in titanium alloy (Ti–6Al–4V) with complex geometry and internal structures are reported. Important parameters and restrictions in the production of complex parts, including support structures, maximum overhanging angle and internal structure are also described.

1. Introduction

Implant materials for fracture fixation must be strong, ductile, and biocompatible in order to fit the bone structure. Currently, the main materials used for this purpose are metals such as stainless steel, cobalt chromium alloys, or commercially pure titanium. However, titanium has long been the material of choice for the maxillofacial application.

In many countries, surgeons prefer not to remove the implanted material. One of the reasons may be that the removal of plates and screws used in fixing facial fractures, for example, often means an additional major surgical intervention. Although titanium is more expensive than steel, it can be more cost-effectively produced in the long run due to its favorable characteristics.

When compared to steel and its components, titanium is physiologically inert, and its unmatched tissue tolerance has been scientifically and clinically proven [1]. According to Williams [2], titanium and several of its alloys have been confirmed as one of the most effective groups of traditional biomaterials and are still the materials of choice for the application of many structural implantable devices. This may be due to the fact that titanium provides an exceptional corrosion resistance in the physiological environment and along with a physiological indifference imparts excellent soft and hard tissue biocompatibility. However, the clinical success of temporary or permanent titanium implants or prostheses does not rely only on favorable tissue reactions and excellent corrosion resistance but also on their functional design.

Design priorities for a device are basically established to attend its structural, functional, and shape features. The implant intended application (used for the support of the locomotory system or the replacement of organs) will determine what materials, design, and manufacturing processes should be used. Presently, there is a great tendency to produce customized implants. Manufacturing of customized maxillofacial implants involves several steps and it usually begins with the fabrication of physical models of the patient's skull using CT scans and current RP techniques. These models are used specially for diagnosis and treatment planning. Prosthesis design can also be made by using physical biomodels as templates. However, the development of a prosthesis model must be reversed engineered to transfer its design to a software environment and then be manufactured. Many related publications discuss the use of biomodels generated by the use of rapid prototyping for diagnostics, operation planning [3] and implant preparation [4,5], even in a virtual environment [6–10]. Several authors pointed out some advantages of using implants designed to attend the needs of each individual: improved operative planning and diagnosis, measurement accuracy, implant conforming the patient's anatomy, reduced surgery time, and more satisfactory aesthetic results [11–13].

However, the choice of material and design cannot be made separately from the fabrication process. The complexity of the anatomical region and prosthetic design exert important influences on the choice of the optimum manufacturing process for the referred part, or parts.

According to Lohfeld et al. [14], the interaction between physical and digital models can lead to inaccuracies and errors. Furthermore, when the process of prosthesis manufacture involves different specialists in different locations, the risk of inaccuracy and error may increase. In addition, the production time for implants is prolonged. To save time and to retain high precision, software should be used to replace the design steps involving physical

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doi:10.1016/j.matdes.2010.02.050

models. Conventional software is capable of performing this task, when it is properly used.

In some studies, digital design and RP techniques were used for direct manufacturing of an implant model [15], but they do not make references to any suitable material for implantation. Lohfeld et al. [14] demonstrated the generation of customized prosthesis using a standard digital design route and a manufacturing process. However, the literature review confirms that there have been no major publications involving design and manufacturing of customized prostheses with suitable materials used for implantation. In this study, the design and manufacturing of a customized implant prior to a surgical procedure are described.

2. Experimental procedure

2.1. Design process

To begin the study, a Computer Tomography of one patient's skull was taken. With CT data images, it was possible to visualize the osseous structure of the skull, as well as the regions affected by a tumor. To obtain the 3D visualization, some software such as Materialise Mimics™ is able to join the CT data slices to produce an accurate 3D representation model. To obtain a virtual model with an appropriate accuracy, some specifications were required, such as maximum of 1.0 mm of slice thickness, 1.0 mm of reconstruction distance and a 512×512 matrix.

The first step for the implant design was to remove the area affected by the tumor. After resection, the file was manipulated in Rhinoceros software. For this study, a mirroring operation using a symmetry plane was enough to generate the 3D implant model on the left side, using a bone structure from a non-injured site as a reference. Therefore, it was possible to design the suitable shape for the implant. The virtual models are shown in Fig. 1.

When the prosthesis shape is well defined, the 3D digital model may be transformed in a 3D physical model. The digital model must be in STL file format, and then prepared for the rapid prototyping process (generating a series of slices that represent the model cross sections, made by the software VisCAM RP).

2.2. Manufacturing

Laser sintering of prototypes or parts using metallic powder as base material has reached a certain level of quality in regard to "simple" geometries. Accomplishing complex geometries and complex internal structures have proved to be a great challenge. The laser sintering process can provide functional and mechanical optimization, and weight reduction. The processing parameters of titanium and its alloys also represent a challenge.

During the sintering process, metal powder is fused into a solid part by melting it locally and by using a laser beam directed by a computer which scans the powder surface horizontally (*x–y*-plane). The process operates on the layer-by-layer principle (Fig. 2). After the last part of one layer is fused, the building platform is lowered vertically (*z*-direction) by one layer thickness and the next layer is prepared by a powder feeder and recoater. After recoating, the local fusing starts again on the newly applied layer. The process is repeated until the part is completed. Afterwards, the building platform is removed from the machine and the part with its most necessary support structure is removed from it.

The Ti–6Al–4V powder that was tested by the use of the master alloy concept in which pure titanium powder is mixed with powder containing 60 wt.% of aluminum and 40 wt.% of vanadium. The powder was mixed for 1 h in a conventional tumbling mixer to achieve homogenous distribution of the alloying elements. The particle size, determined by laser method, was about 48 μm, which indicates that the powder can be processed with layer height of 50 μm. All laser sintering tests were produced using EOSINT M250X running under argon atmosphere. Test specimens were laser sintered onto a pure Ti plate of size $100\,mm \times 100\,mm \times 10\,mm$ mounted on a heating plate at 230 °C. The Ti plate was sand-blasted and cleaned with acetone before installing it into the machine. The laser power was set constantly at 195 W. The laser sintering parameters (hatch distance of 0.05 mm, 0.075 mm

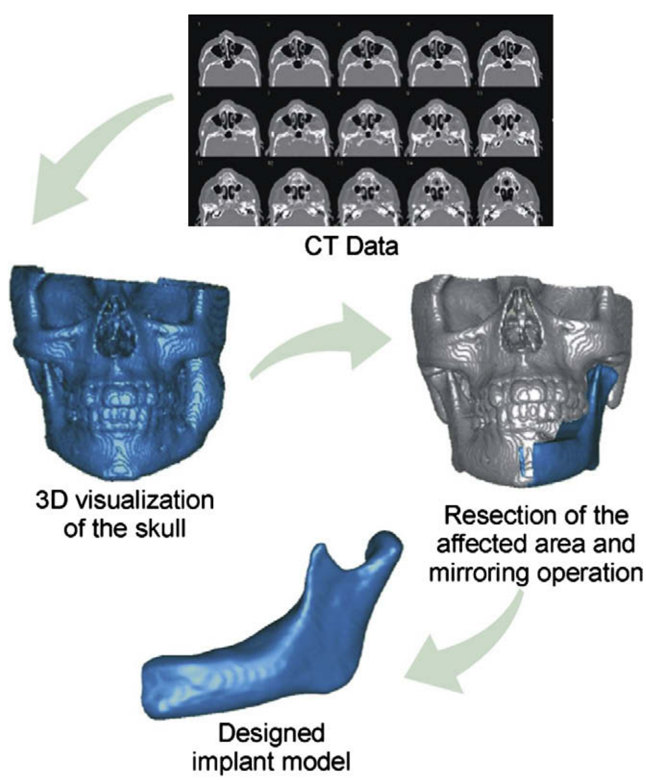

Fig. 1. Steps to design a mandible customized implant.

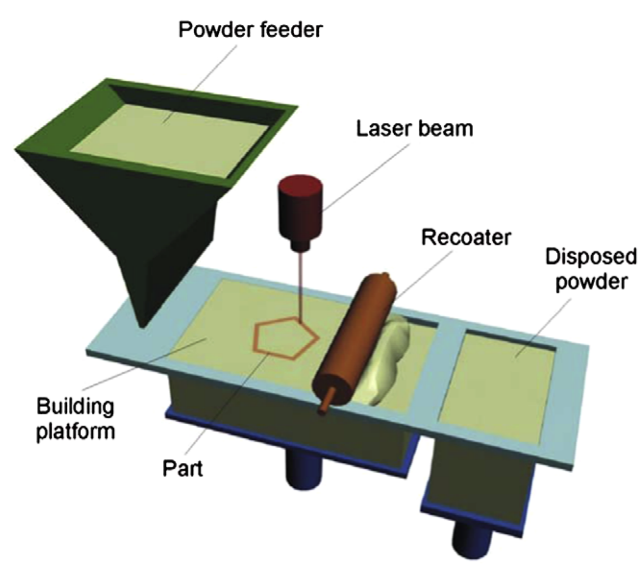

Fig. 2. Principle of laser sintering process.

and 0.1 mm; laser scan speed of 50 mm/s and 100 mm/s) were combined in order to obtain optimized mechanical properties.

Before the laser sintering started, it was necessary to wait for approximately 20 min to achieve an oxygen level of <0.2% (measured by the O_2-sensor at the top of the building chamber). In the meanwhile, the heat plate was heating up until the set temperature was reached.

Each material and laser sintering machine have their own limit angle to build parts. In order to test what would be the most appropriate angle for the materials and machines used in the project, test specimens were built (Fig. 3) to investigate the relation between the angle and the possibility of building the parts. Model inclination from 0° to 45° was tested.

The generation of support structures was investigated, as well as the possibility of building the part with a different internal structure. VisCAM RP software package was used to generate these structures (Marcam Engineering, Germany). Each RP software enables the generation of different support configurations based on the part geometry. For this study, the support patterns provided by VisCAM RP software were manufactured. Parts at an angle under a defined limit angle with the platform need to be supported. However, the configuration of the support structure must be suitable for each geometry. Different support structures, (whose thickness is function of the laser spot size) were investigated in order to build the free-form implant and are illustrated in Fig. 4.

To use the full potential of freeform fabrication techniques, complex internal structures can be combined with other geometric features as shells. Separating parts in shell and core volumes enables new solutions not only for lightweight parts which need a "hard shell" and a "less hard core" but also for parts with internal functionality. Consequently, both volumes produced in one manufacturing process result in considerable savings in powder material, weight, and energy consumption during processing.

Aiming to evaluate the possibility of laser sintering lightweight parts, different internal structures (provided by the software package) were investigated. Next, the feasible structures were selected and inserted into the mandible model.

3. Results and discussion

3.1. Laser sintering parameters

In order to study the laser sintering parameters, test specimens were produced varying hatch distance and scan speed. The obtained final densities (obtained using Archimedes principle) and hardness (HV) are summarized in Table 1.

Fig. 3. Test cones for the determination of a maximum overhang angle.

Table 1
Final densities and hardness for the specimens varying scan parameters.

Specimen	Hatch distance (mm)	Scan speed (mm/s)	Final density (%)	Hardness (HV1)
1	0.05	50	97.6	515
2	0.05	50	96.2	515
3	0.05	50	97.5	515
4	0.05	50	96.4	515
5	0.05	100	93.2	378
6	0.05	100	94.9	439
7	0.05	100	92.7	515
8	0.05	100	92.9	439
9	0.075	50	95.2	613
10	0.075	50	95.8	613
11	0.075	100	92.4	515
12	0.075	100	92.9	515
13	0.1	50	93.6	439
14	0.1	50	93.7	515
15	0.1	100	92.8	515
16	0.1	100	93.0	515

Due to the best results (97.6% final density and 515 HV), the combination of the parameters 0.05 mm (hatch distance) and 50 mm/s (scan speed) was chosen to the production of the models.

3.2. Model inclination

It is possible to build the part at an angle of ($0 < \alpha < 90°$) with a satisfactory surface finish and adequate adhesion to the plate. Without support, only a restricted angle or overhanging length can be built. Below this angle, the laser sintering process cannot be used directly, but it requires support structures to make the parts adequately adhere to the plate.

Structures with angles under 34° were not possible to build as they were removed from the platform. The machine stops the process automatically when the part (or some fragment) is not suitably fixed on the platform. Thus, an angle of 35° was defined as the minimum angle in which the part can be build without support structures, otherwise it will be removed from the plate and the process will fail.

3.3. Support structures

Fig. 5 shows a detailed view of two different tested geometries. The support structure shown in Fig. 5A has a poor surface finish. The reason for this is that the power of the laser beam is too high in some regions where the powder is not supported by the platform or the sintered material. When it occurs, the powder layers placed below will also be affected by the laser and not allow a good quality surface finishing.

The probability of a good surface finish is higher when the support structure is thinner (Fig. 5B) as a larger area on the part surface will be in contact with the supports and not only directly over the powder. Nevertheless, the laser sintering process will take longer due to the greater amount of structures and the larger scanning area. Depending on the size and the amount of supports, however, it can be difficult to remove them and to obtain a suitable surface finish. Therefore, a designed model was manufactured with the use of a thin support structure (Fig. 6).

Model orientation is also an important parameter. The part can be rotated in order to generate a smaller supported area and to reduce the time by removing the supports, as illustrated in Fig. 7. The disadvantage of this procedure is that the model may become too high and the time of the process may increase significantly.

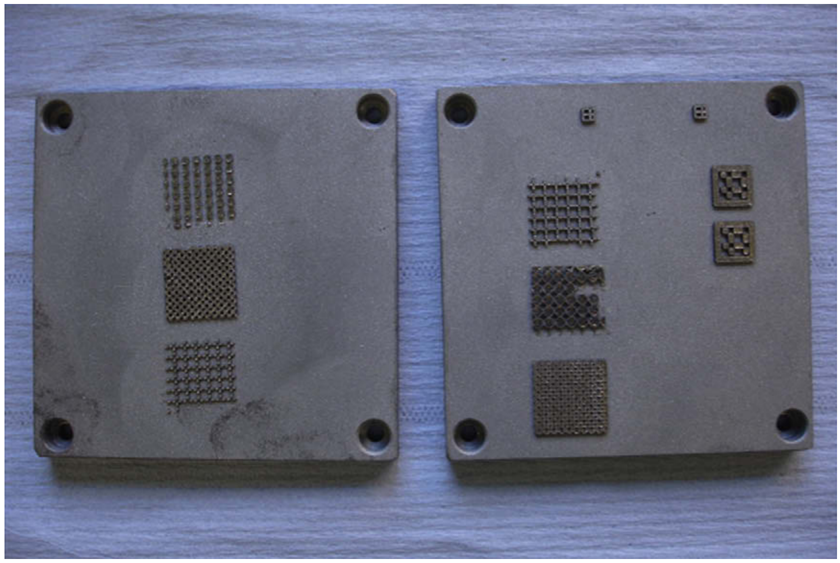

Fig. 4. Tested geometries for the support structures.

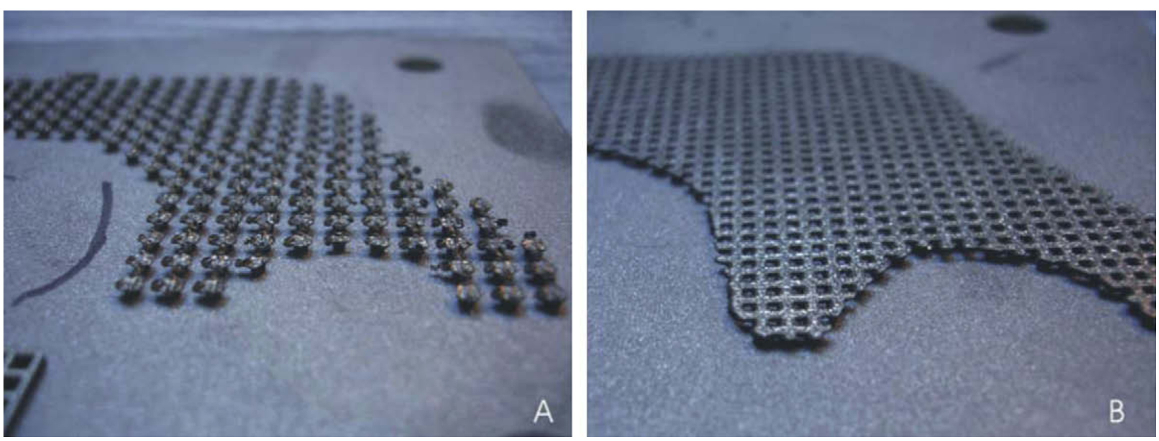

Fig. 5. Examples of support structures investigated. (A) Larger support structure. (B) Thinner support structure.

Fig. 6. Model of the implant built by DMLS process. Due its complex geometry, support structures were built together to make the laser sintering process possible.

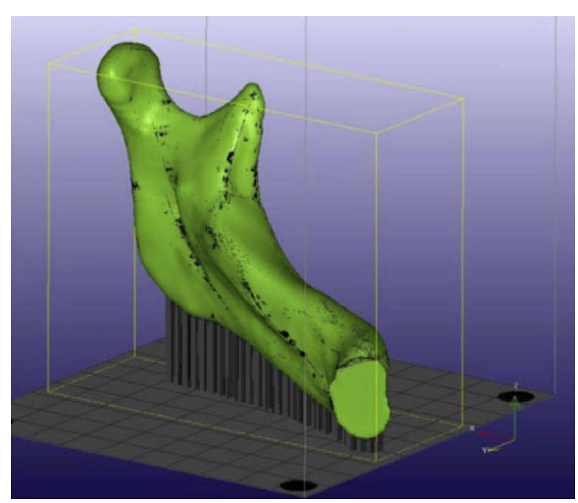

Fig. 7. Rotation of the implant model to reduce the supported area.

3.4. Internal structure

As described by Lohfeld et al. [14], a hollow prosthesis not only benefits from being lightweight, but can also be produced faster. The production time of solid free-form fabrication processes strongly depends on the area to be scanned with the laser in each layer. In this way, the production time can be decreased and the

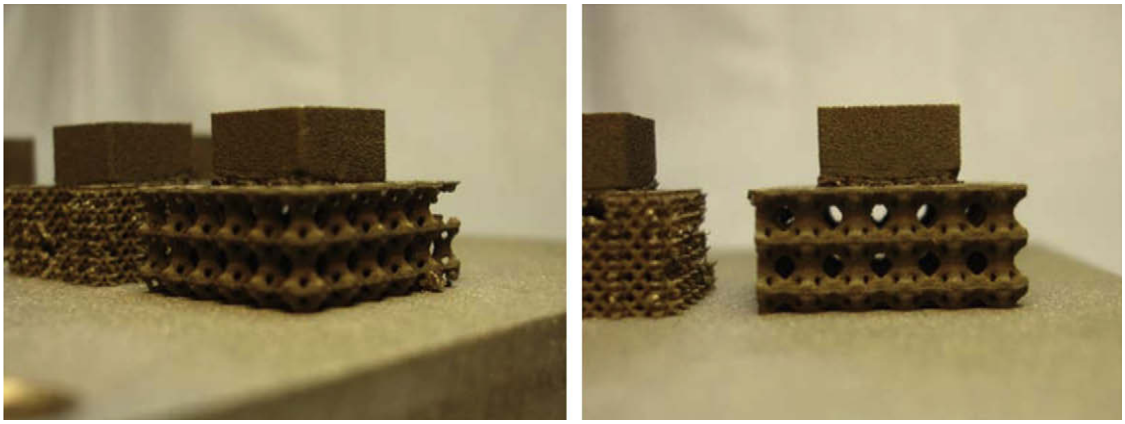

Fig. 8. Tested internal structures to be inserted into the implant model.

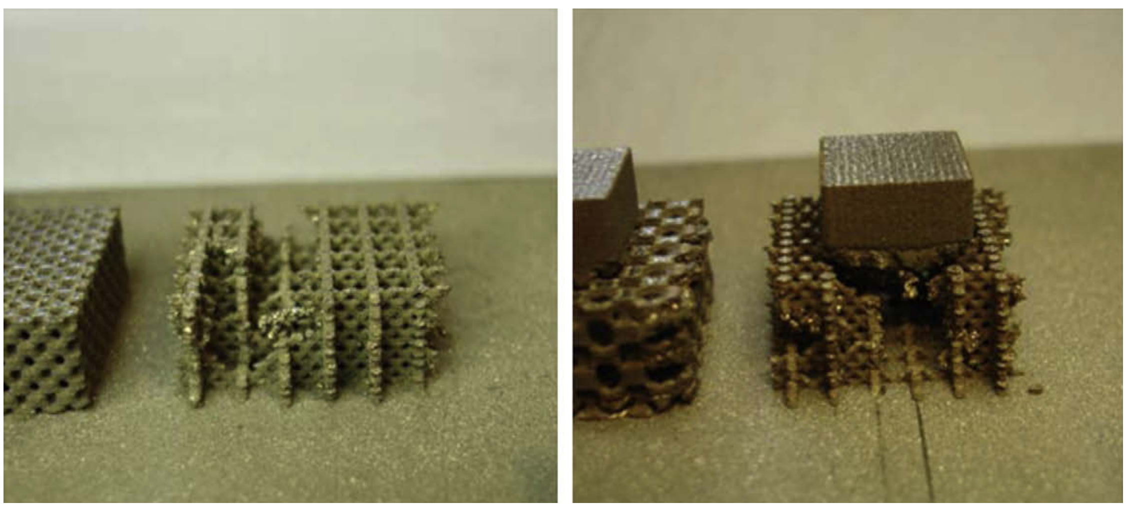

Fig. 9. Tested internal structures which did not performed successfully.

performance of the process can be increased with the use of internal structures.

The possibilities of internal structures provided by the software package were built. Some examples of the use of internal structures are shown in Fig. 8. In both cases, the laser sintering process was competed successfully. It is possible to note that the edges are well defined and the parts present good surface finishing. To the other tested internal structure possibilities available in the software (Fig. 9), the laser sintering process did not performed appropriately, being the process interrupted automatically before its end. The reason of the choice of one specific structure are the feasibility of its geometry, the surface finishing and the process time.

Thus, one of the feasible possibilities for internal structures was selected (spherical structure) and the mandible model was produced, this time not completely filled inside, but with a porous internal configuration (Fig. 10). Producing the parts with the use of a porous internal structure is a feasible way to reduce the weight and to guarantee the strength. Creating internal structures by copying the internal design of a human bone or implementing reservoirs for long term medication are also functions which may be integrated.

One of the disadvantages of manufacturing an internal structure is that the way to remove the powder out of the part must be previously designed, otherwise the non-sintered powder may remain inside and consequently the part will not become lightweight. Models with open-cells suggest the possibility of facing this problem as well as the designing of holes which enables powder removal.

3.5. Dimensional control

In order to validate the dimensional precision of the laser sintering process, the surface of the built part (Fig. 11) was scanned using a three-dimensional laser scanning system with a 150 mm lens, whose accuracy is 0.035 mm. The model was digitized with a resolution (distance between the points) of 0.1 mm. Through this analysis, it was possible to compare the original CAD three-dimensional model with the physical one, as shown in Fig. 12.

Most part of the scanned area presents a difference of no more than 0.05 mm (green area) when compared with the CAD 3D model. Some specific regions found in the borders present a higher value, which may be attributed to the laser strategy.

4. Conclusions

This research study involved different areas including medicine, physics, engineering, and design. The manipulation of the computerized tomography and the CAD model was based essentially on mirroring operations and product design. After that, the suitable

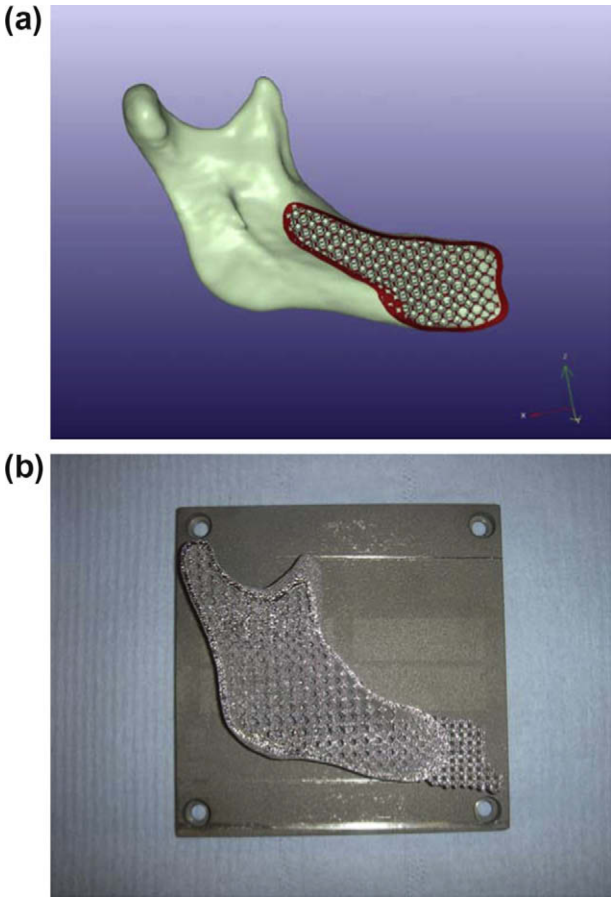

Fig. 10. Human mandible implant – with visible complex internal structure. (a) Virtual model. (b) Laser sintered model.

Fig. 11. 3D physical model built based on 3D CAD data.

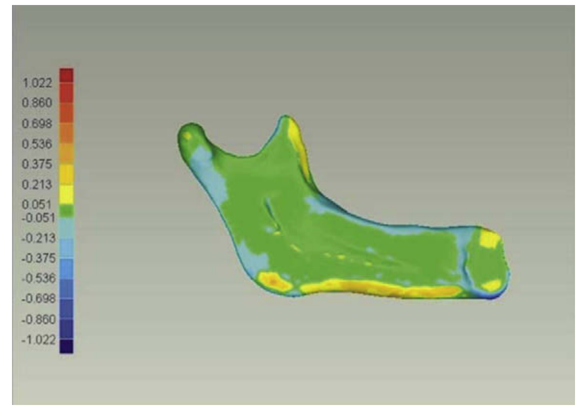

Fig. 12. Three-dimensional comparison (in mm) between the physical models, produced through the laser sintering process, and the CAD original 3D model.

fabrication process must be selected as well as the material. In this case, direct metal laser sintering and the alloy Ti–6Al–4V were chosen.

The different parameters of the process were investigated, such as support structures, inclination and orientation of the model and its internal structure. The process dimensional accuracy was also explored.

The results proved that it is feasible to laser sinter Ti–6Al–4V in EOSINT M250X. By exploring the analysis of the different laser sintering parameters, it was possible to build a free-form part with a complex geometry and complex details. In the future, other geometries can be investigated in order to define all the parameters of this process chain. A porous internal structure can be used to reduce the weight and guarantee the strength at the same time. This results in considerable savings in powder material and weight as well as energy consumption during processing.

Currently, this process is only suitable for special market fields like the parts which have a great aggregate value, for example, automotive and aerospacial parts, medical implants and devices, architectural parts and design objects. The reason is that the costs associated with this manufacture process are still very high considering that a great amount of parts will not be produced. Rapid prototyping can fulfil the customers' demands for a mould to produce in small series, or need small amounts of a certain product. However, it has some disadvantages, such as poor surface finish, relatively small building area, few different material possibilities and relatively high costs associated with the process. The ability to respond quickly, accurately and cheaply brings rapid prototyping into the mainstream production scenario. The advances in this area cross the line from prototype to production economics. Rapid prototyping brings more than just an alternative way to create a commercial object. It brings the ability to bring to the market products that would be otherwise cost prohibitive, impossible to make, and products that carry integrated service values: custom-made, made of point of need, made on demand.

Acknowledgements

The authors would like to thank the National Council for Scientific and Technological Development (CNPq) for the financial support and the Fraunhofer Institute IFAM, Germany, for the technical support in performing the laser sintering tests.

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